



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------------|
| 10/630,627 | 07/29/2003 | Joseph C. Maley | ACRY4.CIP | 9066 |
| 6980 7590 06/26/2008 TROUTMAN SANDERS LLP 600 PEACHTREE STREET, NE ATLANTA, GA 30308 | | | EXAMINER AHMED, HASAN SYED | |
| | | | ART UNIT 1618 | PAPER NUMBER |
| | | | MAIL DATE 06/26/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,627

Applicant(s)

MALEY ET AL.

Examiner

HASAN S. AHMED

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-17 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,4 and 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11-17 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/5/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

- Receipt is acknowledged of Applicants' amendment and IDS, both filed on 7 February 2008
- The 35 USC 112 new matter and enablement rejections of the previous Office action are withdrawn in view of the amendment and remarks.

* * * * *

Claim Objections

Claims 14 and 16 are objected to because of the following informality: they lack a subject between "The" and "of Claim 11". Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-17 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As amended, the instant claim set recites the limitation "hydrophilic polymer network." After carefully examining the instant disclosure, the examiner respectfully

Art Unit: 1618

submits that support for these amendments is lacking and the addition of said limitation is new matter.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Asmus (U.S. Patent No. 5,270,358).

Asmus discloses a transdermal composition comprising a hydrogel (see col. 2, lines 32-38). The disclosed composition is the instant composition as claimed:

- the hydrogel of instant claim 11 (see col. 6, line 31);
- the active agent of instant claim 11 (see col. 12, lines 12-26);
- the humectant (e.g. glycerol) of instant claim 11 (see col. 9, lines 61-62);
- the moisture content of instant claim 11 (see col. 3, line 10; examples 87 and 88);
- the organic acid of instant claim 11 (see col. 12, line 42 – i.e. antibiotic; e.g. penicillin, which is a weak organic acid);
- the moisture management system (as disclosed in pages 23-24 of the Specification, i.e. guar gum) of instant claim 12 (see col. 6, line 68);

- the attachment element (adhesive) of instant claim 13 (*see* col.2, lines 32-38);
- the polyacrylamide of instant claim 14 (*see* col. 6, line 66);
- the antibacterial (antimicrobial) compounds of instant claim 15 (*see* col. 12, lines 12-26);
- the glycerol of instant claim 16 (*see* col. 9, lines 61-62); and
- the moisture content of instant claim 17 (*see* col. 3, line 10; examples 87 and 88).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Asmus (U.S. Patent No. 5,270,358).

Asmus discloses a transdermal composition comprising a hydrogel (*see* above).

Asmus explains that the disclosed invention provides utility for skin adhesive applications (*see* col. 4, line 26).

While Asmus does not explicitly teach the percentages of instant claims 21-23, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through

routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a composition comprising a hydrogel, at least one active agent, at least one humectant, as taught by Young, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful in cleansing skin, as explained by Young, et. al.

* * * * *

Response to Arguments

Applicants' arguments filed 7 February 2008 have been fully considered but they are not persuasive.

Applicants argue that Asmus discloses a high moisture vapor transmission rate and moisture removal while the instant application involves moisture delivery. See remarks, pages 8-11.

At the outset, it should be noted that the amended claim language "hydrophilic polymer network" was not considered because it is deemed to be new matter (*see* 35 USC 112 rejection, above).

The instant application claims a very broad treatment surface, i.e. any "dermal structure." The Asmus invention addresses use on skin surfaces, which are hydrophobic. However, the Asmus reference discloses water content within the range recited in instant claim 17 (*see* examples 87 and 88). As such, examiner respectfully submits that the Asmus invention would deliver moisture if applied to a hydrophilic surface, such as a nail structure, which is encompassed by the broad scope of the instant claims. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433. Furthermore, the claim does not specify the extent of moisture at the dermal structure; there is no indication in the claim language that the dermal structure will be subject to increased moisture as a result of the diffusion gradient, as opposed to ambient moisture resulting from water content in the claimed composition.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618